



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Subhashis Banerjee et al.

Serial No.: 10/623,065

ART UNIT: 1642

Filed: July 18, 2003

EXAMINER: David J. Blanchard

Entitled: TREATMENT OF CORONARY  
DISORDERS USING TNF $\alpha$   
INHIBITORS

Attorney Docket No.: BBC-202

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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9/28/2005

Date

  
Daphne Miller

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98**

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

**U.S. Patent Documents**

Salfeld et al., July 18, 2000, U.S. Patent No. 6,090,382

Salfeld et al., July 10, 2001, U.S. Patent No. 6,258,562

Salfeld et al., January 21, 2003, U.S. Patent No. 6,509,015

Foreign Patent Documents

Kempeni et al., December 19, 2002, WO 02/100330

Fischkoff et al., January 15, 2004, WO 2004/004633

Krause et al., February 26, 2004, WO 2004/016286

Kaymakcalan et al., May 6, 2004, WO 2004/037205

Salfeld et al., August 14, 1997, WO 97/29131

Other Publications

Balbay et al. (2001) *Angiology*. 52:109

Belosjorow et al. *Am. J. Physiol. Heart Circ. Physiol.* 2003 Mar;284(3):H927-30. Epub 2002 Dec 05

Berk and Harris (1995) *Adv. Intern. Med.* 40:455-501

Bozkurt et al. *Circulation*. 2001 Feb 27;103(8):1044-7

Bult, H. (2000) *Trends in Pharmacological Sciences* 21:274-279

Burns et al. (2002) *J Am Coll Cardiol.* 39:30)

Chung et al. *Circulation*. 2003 Jul 1;107(25):3133-40

Clagett et al. (1986) *J. Vasc. Surg.* 3:10-23

Clausell et al. *Br. Heart J.* 1995 Jun;73(6):534-9

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Cusack et al. *J. Am. Coll. Cardiol.* 2002 Jun 19;39(12):1917-23

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Deswal et al *Circulation*. 1999 Jun 29;99(25):3224-6

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Herskowitz et al. *Am. J. Pathol.* 1995 Feb;146(2):419-28

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Kumar and Lindner (1997) *Arterioscler. Thromb. Vasc. Biol.* 17:2238

- Kumar, et al. (1997) *Circulation* 96(12):4333-4342
- Kurrelmeyer et al. *PNAS USA* 2000 May 9;97(10):5456-61
- Lentz SR et al. (2002) *Circulation* 106(7):842-6
- Levine et al. *N. Engl. J. Med.* 1990 Jul 26;323(4):236-41
- Li et al. *Am. Heart J.* 1999 Jun;137(6):1145-52
- Libby *Circulation* 1995;91:2844-50
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- Lissoni et al. *Eur. J. Med.* 1992 Sep;1(5):277-80
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- Mendall et al. (1997) *Heart* 78(3):273
- Meng et al. *Shock.* 2002 May;17(5):345-53
- Nakamura, et al. *J. Cardiol.* 2003 Jan;41(1):41-2
- Old, L. (1985) *Science* 230:630-632
- Orrego, et al. (1999) *Cardiologia* 44(7)621)
- Pudil et al. *Clin. Chim. Acta.* 1999 Feb;280(1-2):127-34
- Ridker et al. *Circulation.* 2000 May 9;101(18):2149-53
- Shames et al. *Shock.* 2002 Feb;17(2):114-9
- Smith et al. *Br. J. Dermatol.* 2001 Mar;144(3):597-600
- Soran et al. *Br. J. Clin. Pharmacol.* 2001 Feb;51(2):191-2
- Squadrito et al. *Eur. J. Pharmacol.* 1993 Jun 24;237(2-3):223-30
- Sugano et al. (2002) *FASEB J* 16:1421
- Sundell CL et al. (2003) 305(3):1116-23
- Tanaka et al. *Arterioscler. Thromb. Vasc. Biol.* 1996 Jan;16(1):12-8
- Torre-Amione et al. *J. Am. Coll. Cardiol.* 1996 Apr;27(5):1201-6
- Valgimigli et al. *Circulation.* 2003 Jan 21;107(2):264-70
- Yamashita et al. *Br. J. Pharmacol.* 2000 Oct;131(3):415-22
- Zhou et al. *Atherosclerosis.* 2002 Mar;161(1):153-9
- Zimmerman et al. *Am. J. Physiol. Regul. Integr. Comp. Physiol.* 2002 Aug;283(2):R505-12
- Moreland, et al. *J. Invest. Med.* (1996) Vol. 44, 235A

Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first Office action after the filing of a request for continued examination filed under 37 CFR §1.114. Pursuant to 37 CFR §1.97(b)(4), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Application Number	10/623,065
Filing Date	July 18, 2003
First Named Inventor	S. Banerjee
Art Unit	1642
Examiner Name	David J. Blanchard
Attorney Docket Number	BBC-202

## **FOREIGN PATENT DOCUMENTS**

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
		WO 02/100330	12-19-2002	Abbott Biotechnology Ltd.	
		WO 04/004633	01-15-2004	Abbott Biotechnology Ltd.	
		WO 04/016286	02-26-2004	Abbott Laboratories (Berm	
		WO 04/037205	05-06-2004	Abbott Biotechnology Ltd.	
		WO 97/29131	08-14-1997	BASF Aktiengesellschaft	

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		BALBAY et al. "Circulating Interleukin-1 Beta, Interleukin-6, Tumor Necrosis Factor-Alpha, and Soluble ICAM-1 in Patients with Chronic Stable Angina and Myocardial Infarction" (2001) Angiology. 52:109			
		BELOSJOROW et al. "TNF- $\alpha$ antibodies are as effective as ischemic preconditioning in reducing infarct size in rabbits" (2003) Am. J. Physiol. Heart Circ. Physiol. Mar; 284(3):H927-930.			
		BERK, BC et al. "Restenosis After Percutaneous Transluminal Coronary Angioplasty: New Therapeutic Insights From Pathogenic Mechanisms" (1995) Adv. Intern. Med., 40:455-501			
		BOZKURT et al. "Results of Targeted Anti-Tumor Necrosis Factor Therapy with Etanercept (ENBREL) in Patients with Advanced Heart Failure" (2001 Feb 27), 103(8):1044-7			
		BULT, H. "Restenosis: a challenge for pharmacology" (2000) Trends in Pharmacological Sciences, 21:274-279			
		BURNS, et al. "The Relationships of Left Ventricular Ejection Fraction, End-Systolic Volume Index and Infarct Size to Six-Month Mortality After Hospital Discharge Following Myocardial Infarction Treated by Thrombolysis" (2002) J. Am Coll Cardiol. 39:30			
		CHUNG, et al. "Randomized, Double-Blind, Placebo-Controlled, Pilot Trial of Infliximab, a Chimeric Monoclonal Antibody to Tumor Necrosis Factor- $\alpha$ , in Patients with Moderate-to-Severe Heart Failure" (2003 Jul 1) Circulation, 107(25):3133-40			
		CLAGETT, et al. "Morphogenesis and clinicopathologic characteristics of recurrent carotid disease" (1986) J. Vasc. Surg. 3:10-23			
		CLAUSELL, et al. "Expression of tumour necrosis factor $\alpha$ and accumulation of fibronectin in coronary artery restenotic lesions retrieved by atherectomy" (1995) Br. Heart J., 73(6):534-539			
		CLELAND, et al. "Clinical Trials Update: Capricorn, Copernicus, Miracle, Staf, Ritz-2, Recover and Renaissance and cachexia and cholesterol in heart failure. Highlights of the Scientific Sessions of the American College of Cardiology, 2001" (2001 Jun) Eur. J. Heart Fail., 3(3):381-387			

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		CLOWES, et al. "Mechanisms of Stenosis after Arterial Injury" (1983) Laboratory Investigation, 49:208	
		CUSACK, et al. "Systemic Inflammation in Unstable Angina Is the Result of Myocardial Necrosis" (2002 June 19) J. Am. Coll. Cardiol. 39(12):1917-1923	
		de WAARD, et al. "Plasminogen Activator Inhibitor 1 and Vitronectin Protect Against Stenosis in a Murine Carotid Artery Ligation Model" (2002) Arterioscler. Thromb. Vasc. Biol. 22:1978-1983	
		DESWAL, et al. "Safety and Efficacy of a Soluble P75 Tumor Necrosis Factor Receptor (Enbrel, Etanercept) in Patients With Advanced Heart Failure" (1999 Jun 29), Circulation, 99(25):3224-3226	
		FERNS, et al. "Inhibition of Neointimal Smooth Muscle Accumulation After Angioplasty by an Antibody to PDGF" (1991) Science 253:1129	
		FICHTLSCHERER, et al. "Tumor Necrosis Factor Antagonism With Etanercept Improves Systemic Endothelial Vasoreactivity in Patients with Advanced Heart Failure" (2001 Dec 18) Circulation 104(25):3023-3025	
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		HALAWA, et al. "Tumor necrosis factor (TNF- $\alpha$ ) and interleukin 6 (IL-6) plasma levels in patients with acute myocardial infarction" (1999 Mar) Pol. Arch. Med. Wewn. 101(3):197-203	
		HERSKOWITZ, et al. "Cytokine mRNA Expression in Postischemic/Reperfused Myocardium" (1995 Feb) A. J. Pathol. 146(2): 419-428	
		HIRSCHL, et al. "Assessment of myocardial injury by serum tumour necrosis factor alpha measurements in acute myocardial infarction" (1996 Dec) Eur. Heart J. 17(12):1852-1859	

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		IOCULANO, et al. "Tumour Necrosis Factor Mediates E-Selectin Production and Leukocyte Accumulation In Myocardial Ischaemia-Reperfusion Injury" (1995 May) Pharmacol. Res. 31(5):281-288	
		JACKSON, et al. "\-Blockers reduce the incidence of clinical restenosis: Prospective study of 4840 patients undergoing percutaneous coronary revascularization" (2003) Am Heart J. 145:875	
		JACOBS, et al. "Tumor Necrosis Factor-\alpha at Acute Myocardial Infarction in Rats and Effects on Cardiac Fibroblasts" (1999 Nov) J. Mol. Cell. Cardiol. 31(11):1949-1959	
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		KUMAR, A. AND LINDNER, V. "Remodeling with Neointima Formation in the Mouse Carotid Artery After Cessation of Blood Flow" (1997) Artérioscler. Thromb. Vasc. Biol. 17:2238	
		KUMAR, et al. "Remodeling and Neointimal Formation in the Carotid Artery of Normal and P-Selectin-Deficient Mice" (1997) Circulation 96(12):4333-4342	
		KURRELMEYER, et al. "Endogenous tumor necrosis factor protects the adult cardiac myocyte against ischemic-induced apoptosis in a murine model of acute myocardial infarction" (2000 May 9) PNAS USA 97(10):5456-5461	
		LENTZ, et al. "Anticoagulant Responses to Thrombin Are Enhanced During Regression of Atherosclerosis in Monkeys" (2002) Circulation 106(7):842-846	
		LEVINE, et al. "Elevated Circulating Levels of Tumor Necrosis Factor in Severe Chronic Heart Failure" (1990 Jul 26) N. Engl. J. Med. 323(4):236-241	
		LI, et al. "Kinetics of tumor necrosis factor \alpha in plasma and the cardioprotective effect of a monoclonal antibody to tumor necrosis factor \alpha in a acute myocardial infarction" (1999 Jun) Am Heart J. 137(6):1145-52	

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		LIBBY, PETER, MD. "Molecular Bases of the Acute Coronary Syndromes" (1995) Circulation 91:2844-2850		
		LINDNER, et al. "Mouse Model of Arterial Injury" (1993) Circ Res. 73:792		
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		MAEKAWA, et al. "Improved Myocardial Ischemia/Reperfusion Injury in Mice Lacking Tumor Necrosis Factor- $\alpha$ " (2002 Apr 3) J. Am. coll. Cardiol. 39(7): 1229-1235		
		MENDALL, et al. "Relation of serum cytokine concentrations to cardiovascular risk factors and coronary heart disease" (1997) Heart 78(3):273-277		
		MENG, et al. "The Interaction Between HSP70 and TNF- $\alpha$ Expression: A Novel Mechanism For Protection of the Myocardium Against Post-Injury Depression" (2002 May) Shock 17(5):345-353		
		NAKAMURA, et al. "Induction of Left Ventricular Remodeling and Dysfunction in the Recipient Heart Following Donor Heart Myocardial Infarction: New Insights into the Pathological Role of Tumor Necrosis Factor- $\alpha$ From a Novel Heterotopic Transplant-Coronary Ligation Model" (2003 Jan) J. Cardiol. 41(1):41-42		
		OLD, LLOYD J. "Tumor Necrosis Factor (TNF)" (1985) Science 230:630-632		
		ORREGO, et al. "Coronary angioplasty and coronary artery remodeling" (1999) Cardiologia 44(7):621-625		
		PUDIL, et al. "Cytokines and adhesion molecules in the course of acute myocardial infarction" (1999 Feb) Clin. Chim. Acta. 280(1-2):127-134		

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		SHAMES, et al. "Ischemia Alone Is Sufficient To Induce TNF- $\alpha$ mRNA and Peptide In The Myocardium" (2002 Feb) Shock 17(2):114-119				
		SMITH, K.J. AND SKELTON, H. "Common variable immunodeficiency treated with a recombinant human IgG, tumour necrosis factor- $\alpha$ receptor fusion protein" (2001 Mar) Br. J. Dermatol. 144(3):597-600				
		SORAN, et al. "The pharmacokinetics of etanercept in patients with heart failure" (2001 Feb) 51(2):191-192				
		SQUADRITO, et al. "Tumor necrosis factor involvement in myocardial ischaemia-reperfusion injury" (1993 Jun 24) Eur. J. Pharmacol. 237(2-3):223-30				
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
				Application Number	10/623,065
				Filing Date	July 18, 2003
				First Named Inventor	S. Banerjee
				Art Unit	1642
				Examiner Name	David J. Blanchard
Sheet	7	of	7	Attorney Docket Number	BBC-202

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
		YAMASHITA, et al. "The involvement of cytokines in the second window of ischaemic preconditioning" (2000 Oct) Br. J. Pharmacol 131(3):415-422		
		ZHOU, et al. "Effect of anti-tumor necrosis factor- $\alpha$ polyclonal antibody on restenosis after balloon angioplasty in a rabbit atherosclerotic model" (2002 Mar) Atherosclerosis 161(1):153-159		
		ZIMMERMAN, et al. "Lack of TNFalpha attenuates intimal hyperplasia after mouse carotid artery injury" (2002 Aug) Am. J. Physiol. Regul. Integr. Comp. Physiol 283(2): R505-512		
		MORELAND, et al. "Double Blind Placebo Controlled Trial of Tumor Necrosis Factor Receptor Fusion Protein (TNFR:Fc) In Active Rheumatoid Arthritis" (1996) J. Invest. Med. 44:235A		

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